DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR - 5 1999

4443 '99 APR -7 A9:51

The Honorable Ralph M. Hall
House of Representatives
Washington, D.C. 20515-4304

Dear Mr. Hall:

Thank you for your letter of March 22, 1999, on behalf of several of your constituents, regarding dietary supplements containing ephedrine alkaloids. Ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. The ephedrine alkaloids in dietary supplements are naturally occurring stimulants and usually are derived from one of several species of herbs of the genus Ephedra, sometimes called Ma huang or Chinese Ephedra.

On June 4, 1997, the Food and Drug Administration (FDA or the Agency) published a proposed rule in the Federal Register (FR) regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. In the proposed rule, the Agency is proposing:

- to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids;

- to require that the label of dietary supplements that contain ephedrine alkaloids state, "Do not use this product for more than 7 days";

- to prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids;

- to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building);

95N-0304

E
C3687/ANS

- to require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that, "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and

- to require specific warning statements to appear on product labels.

The proposal also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements.

FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products which contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors, and headaches, to seizures, strokes, and death. As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products which contained, or were suspected of containing, ephedrine alkaloids. The adverse events reports showed consistent patterns of illness and injury among otherwise healthy individuals and those with underlying diseases or conditions. FDA continues to receive additional reports of adverse events associated with the use of these products.

The proposed measures were developed based on FDA's review of its adverse event reports, the scientific literature, and public comments reviewed by the Agency, including comments generated by an October 1995 advisory working group public meeting and an August 1996 public meeting of FDA's Food Advisory Committee. These experts suggested a number of steps the Agency might take to reduce injuries associated with the use of dietary supplements containing ephedrine alkaloids. If implemented, the proposed rule will reduce the risk of adverse events for consumers who use these products.

FDA allowed a 75-day comment period on the proposed rule. On September 18, 1997 (62 FR 48968), that comment period was reopened for an additional 75 days until December 2, 1997. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Kathryn S. Hudson

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: Dockets Management Branch
(Docket #95N-0304)

RALPH M. HALL
4TH DISTRICT, TEXAS

Congress of the United States
House of Representatives
Washington, DC 20515–4304

COMMERCE
ENERGY AND POWER
RANKING MINORITY MEMBER
HEALTH AND ENVIRONMENT
FINANCE AND HAZARDOUS MATERIALS
SCIENCE
SPACE AND AERONAUTICS
ENERGY AND ENVIRONMENT

March 22, 1999

Ms. Diane E. Thompson
Legislative Affairs
Food and Drug Administration
5600 Fisher Lane
Rockville, MD 20857-0001

Dear Ms. Thompson:

I have received ten postcards on a subject which is within the jurisdiction of your office. These constituents are writing to voice their opposition to a proposed rule (62FED.REG.30678.) Apparently, this rule would limit levels of ephedrine, found in a dietary supplement, known as Ma Huang.

These constituents would like to have their voices counted among those who oppose this proposed rule, and they have asked that I register their comments with your office. In case you need the actual names and addresses of these individuals I am enclosing the cards which have been sent to me. Besides registering the names of these individuals among those opposing this proposed regulation, I also ask that your office send me a brief response explaining the position of the Federal Food and Drug Administration, FDA on this dietary supplement.

You may direct any of your communications to my office, on this subject to Ms. Marsha Shasteen, who can be reached at my Washington office.

Sincerely,

Ralph M. Hall

Ralph M. Hall
Member of Congress

RMH:mes

No. 99 - 2013

Please reply to:
☐ 2221 RAYBURN HOB
WASHINGTON, DC 20515-4304
(202) 225-6673
(202) 225-3332 FAX
e-mail: rmhall@mail.house.gov

☐ COOKE COUNTY COURTHOUSE
GAINESVILLE, TX 76240
(940) 668-6370
(940) 668-6478 FAX

☐ 104 NORTH SAN JACINTO
ROCKWALL, TX 75087-2508
(972) 771-9118
(972) 722-0907 FAX

☐ 114 FEDERAL BUILDING
SHERMAN, TX 75090-5917
(903) 892-1112
(903) 868-0264 FAX

☐ 211 FEDERAL BUILDING
TYLER, TX 75702-7222
(903) 597-3729
(903) 597-0726 FAX

Dear Representative Ralph Hall,

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the level of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid, cold and allergy products, which can be purchased at your local store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and let my voice be heard!

Sincerely (signature) [illegible]

Name [illegible]

Address [illegible]

City [illegible] County DENTON

[illegible] 76202-1511

Dear Representative Ralph Hall,

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the level of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid, cold and allergy products, which can be purchased at your local store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and let my voice be heard!

Sincerely (signature) [illegible]

Name [illegible]

Address [illegible]

City [illegible] County Kaufman

[illegible] 75160-0971

Dear Representative Ralph M. Hall

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the level of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid, cold and allergy products, which can be purchased at your local store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and let my voice be heard!

Sincerely (signature) [illegible]

Name [illegible]

Address [illegible]

City [illegible] County Denton

[illegible] 76266-2617

Dear Representative Ralph HALL,

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the level of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid, cold and allergy products, which can be purchased at your local store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and let my voice be heard!

Sincerely (signature) Emmaline Hawkins

Name Emmaline Hawkins

Address [illegible]

City [illegible] County Collin

TX [illegible] 75098

Dear Representative Ralph M. Hall

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid. Cold and allergy products, which can be purchased at any grocery store without a prescription, contain over ***three times*** the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary

I urge you to [illegible] and [illegible] unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] heard!

Sincerely (signature)

Name

Address

City Hunt County

75189 3041

Dear Representative Ralph Hall,

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid. Cold and allergy products, which can be purchased at any grocery store without a prescription, contain over ***three times*** the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary

I urge you to [illegible] and [illegible] unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] heard!

Sincerely (signature)

Name

Address

City Kaufman County

75142-7343

Dear Senator ~~Kay Bailey Hutchison~~

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid. Cold and allergy products, which can be purchased at any grocery store without a prescription, contain over ***three times*** the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary

I urge you to contact the FDA and [illegible] unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] my voice heard!

Sincerely (signature)

Name

Address

Ralph Hall

Dear Representative Ralph Hall,

I need your help! The FDA has proposed a rule (62FED.REG.30678) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss aid. Cold and allergy products, which can be purchased at any grocery store without a prescription, contain over ***three times*** the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary

I urge you to [illegible] and [illegible] unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] heard!

Sincerely (signature)

Name

Address

Dear Representative Ralph Hall,

I need your help! The FDA has proposed a rule (62FED.REG.3067[illegible]) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss, sinus, and allergy products which can be purchased at the grocery store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] heard!

Sincerely (signature) [illegible]

Name [illegible]

Address [illegible]

City [illegible] County [illegible]

State [illegible] Zip Code [illegible] 3204

Duplicate Card

Dear Representative Ralph M. Hall

I need your help! The FDA has proposed a rule (62FED.REG.3067[illegible]) that restricts ***all*** dietary supplements containing naturally occurring ephedrine alkaloids, the active substances in the herb Ma Huang. This illegally proposed regulation would severely limit the levels of ephedrine found in Ma Huang dietary supplements to a level that renders them useless as a weight loss, sinus, and allergy products which can be purchased at the grocery store without a prescription, contain over three times the ephedrine than the FDA's proposed regulation for herbal supplements.

The FDA has based their proposed rule on anecdotal information. What about the millions of Americans who safely and responsibly consume herbal supplements containing Ma Huang each day? Why is the FDA insisting on restricting my freedoms without any scientific basis or evidence for these restrictions? I strongly believe this rule violates the 1994 Dietary Supplement Health and Education Act, which Congress passed to regulate outrageous and unnecessary actions by the FDA regarding dietary supplements.

I urge you to contact the FDA and stop this unnecessary and illegal action. I ask you, as my elected official, to protect the integrity of DSHEA and [illegible] heard!

Sincerely (signature) [illegible]

Name [illegible]

Address [illegible]

City [illegible] County Hunt

State [illegible] Zip Code 75189 3044